

IN THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the present application.

1-8 (cancelled).

9 (currently amended). A therapeutic combination preparation comprising (a) rotigotine or a metabolite, prodrug or physiologically acceptable salt thereof, and (b) ~~at least one further active ingredient selected from the group consisting of one or more additional active ingredients comprising one or more~~ antidepressants, antipsychotics, sedatives, anxiolytics and and/or anti-migraine agents.

10 (previously presented). A method for treating depression in a mammal, comprising administering a therapeutically effective quantity of rotigotine or a metabolite, prodrug or physiologically acceptable salt thereof, to said mammal.

11 (previously presented). The method of claim 10, wherein the mammal is human.

12 (currently amended). The method of Claim 11, wherein the depression is an endogenous depression ~~or an organic depression not associated with Parkinson's disease.~~

13 (currently amended). The method of Claim [[11]] 12, wherein the endogenous depression is a unipolar depression (major depression) or a depressive episode of a manic-depressive disorder.

14 (currently amended). The method of Claim [[11]] 32, wherein the somatogenic depression is an organic depression ~~which is independent of not associated with~~ Parkinson's disease.

15 (currently amended). The method of Claim [[11]] 32, wherein the somatogenic depression is [[a]] an organic depression associated with Parkinson's disease.~~—associated depression.~~

16 (previously presented). The method of Claim 15, wherein co-medication with another antidepressant is absent.

17 (previously presented). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered parenterally, transdermally or mucosally.

18 (currently amended). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.5 to about 50 mg per day.

19 (previously presented). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.5 to 10 mg per day.

20 (previously presented). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.5 to 5 mg per day.

21 (currently amended). The method of claim [[11]] 10, wherein the rotigotine is administered as a prodrug thereof.

22 (previously presented). The method of Claim 21, wherein the prodrug is an ester, carbamate, carbonate, ketal, acetate, phosphate, phosphonate, sulfate or sulfonate.

23 (currently amended). The method of Claim [[11]] 10, wherein the rotigotine is administered transdermally as rotigotine free base or hydrochloride salt.

24 (previously presented). The method of Claim 23, wherein the rotigotine is formulated as an ointment, paste, spray, film, plaster or iontophoretic device for transdermal administration.

25 (previously presented). The method of Claim 23, wherein the rotigotine is formulated as a plaster having the rotigotine in a matrix comprising an adhesive polymer.

26 (previously presented). The method of Claim 23, wherein a substantially constant plasma level of rotigotine is established.

27 (previously presented). The method of Claim 10, further comprising administering to the mammal ~~at least one additional active ingredient selected from the group consisting of one or more~~ antidepressants, ~~antipsyehotics, sedatives, anxiolyties and anti-migraine agents.~~

28 (currently amended). The combination **preparation** of Claim 9, wherein the **at least one or more additional further** active ingredients **[[is an]] comprise one or more** antidepressants **selected from the group consisting of comprising one or more** selective serotonin reuptake inhibitors, mixed serotonin and noradrenalin reuptake inhibitors, selective noradrenaline reuptake inhibitors, monoamine oxidase inhibitors, alpha2 receptor modulators, serotonin receptor modulators, adenosine antagonists, sigma-opioid receptor ligands, NK antagonists, melatonin antagonists **and and/or** modulators of the hypothalamus-hypophysis-adrenal axis.

29 (new). The method of Claim 10, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in monotherapy.

30 (new). The method of Claim 10, wherein the quantity of rotigotine or metabolite, prodrug or salt thereof is effective for alleviation of symptoms of Parkinson's disease and for treatment of depression.

31 (new). The method of Claim 30, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in monotherapy.

32 (new). The method of Claim 11, wherein the depression is a somatogenic depression.

33 (new). The method of Claim 14, wherein the organic depression is associated with brain tumor, migraine, epilepsy, brain paralysis, arteriosclerosis of the brain, brain trauma, meningitis, stroke, Parkinson Plus syndrome, dementia and/or cerebrovascular disease.

34 (new). The method of Claim 14, wherein the organic depression is associated with Alzheimer's disease.

35 (new). The method of Claim 32, wherein the somatogenic depression is a symptomatic depression.

36 (new). The method of Claim 35, wherein the symptomatic depression is associated with circulatory illness, hypothyroidism, hormone disorder, infectious disease, cancer and/or liver disease.

37 (new). The method of Claim 32 wherein the somatogenic depression is a pharmacogenic depression.

38 (new). The method of Claim 37, wherein the pharmacogenic depression is associated with alcohol, medication and/or drug misuse.

39 (new). The method of Claim 11, wherein the depression is a psychogenic depression.

40 (new). The method of Claim 39, wherein the psychogenic depression comprises at least one of exhaustion depression, neurotic depression and reactive depression as a result of current conflicts or events.

41 (new). The method of Claim 11, wherein the depression occurs in particular circumstances, comprising at least one of postpartum depression, old-age depression, childhood depression, seasonal depression and pubertal depression.

42 (new). The method of Claim 10, wherein the depression is associated with an affective disorder.

43 (new). The method of Claim 42, wherein the affective disorder comprises a recurrent depressive disorder and/or depressive phases in bipolar affective disorder.

44 (new). The method of Claim 11, wherein the depression manifests as depressive symptoms accompanying at least one anxiety disorder, adjustment disorder and/or organic brain disease.

45 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.1 to about 50 mg per day.

46 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.2 to 40 mg per day.

47 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in a dosage of 0.4 to 20 mg per day.

48 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in an amount effective to obtain a plasma rotigotine concentration of 0.05 to 20 ng/ml.

49 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 10 ng/ml.

50 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in an amount effective to obtain a plasma rotigotine concentration of 0.2 to 5 ng/ml.

51 (new). The method of Claim 11, wherein the rotigotine or metabolite, prodrug or salt thereof is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 0.5 ng/ml.

52 (new). The method of Claim 21, wherein the prodrug is administered in an amount effective to obtain a plasma rotigotine concentration of 0.05 to 20 ng/ml.

53 (new). The method of Claim 52, wherein the prodrug is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 10 ng/ml.

54 (new). The method of Claim 52, wherein the prodrug is administered in an amount effective to obtain a plasma rotigotine concentration of 0.2 to 5 ng/ml.

55 (new). The method of Claim 52, wherein the prodrug is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 0.5 ng/ml.

56 (new). The method of Claim 26, wherein the rotigotine is administered in an amount effective to obtain a plasma rotigotine concentration of 0.05 to 20 ng/ml.

57 (new). The method of Claim 26, wherein the rotigotine is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 10 ng/ml.

58 (new). The method of Claim 26, wherein the rotigotine is administered in an amount effective to obtain a plasma rotigotine concentration of 0.2 to 5 ng/ml.

59 (new). The method of Claim 26, wherein the rotigotine is administered in an amount effective to obtain a plasma rotigotine concentration of 0.1 to 0.5 ng/ml.

60 (new). The method of Claim 27, wherein the one or more antidepressants comprise one or more serotonin reuptake inhibitors, mixed serotonin and noradrenalin reuptake inhibitors, selective noradrenaline reuptake inhibitors, monoamine oxidase inhibitors, alpha2 receptor modulators, serotonin receptor modulators, adenosine antagonists, sigma-opioid receptor ligands, NK antagonists, melatonin antagonists and/or modulators of the hypothalamus-hypophysis-adrenal axis.

61 (new). The method of Claim 60, wherein the one or more anti-depressants comprise at least one of sertraline, citalopram, paroxetine, fluoxetine, venlafaxine, milnacipram, mirtazapine, amitriptyline, imipramine, reboxetine, tranylcypromine, clorgyline, and/or nefazodone.

62 (new). The method of Claim 10, further comprising administering to the mammal one or more antipsychotics.

63 (new). The method of Claim 62, wherein the one or more antipsychotics comprise at least one of promethazine, fluphenazine, perphenazine, levomepromazine, thioridazine, perazine, promazine, chlorprothixene, zuclopentixol, prothipendyl, flupentixol, zotepine, benperidol, pipamperon, melperon, haloperidol, bromperidol, sulpiride, clozapine, pimozide, risperidone, quetiapine, amisulpride and/or olanzapine.

64 (new). The method of Claim 10, further comprising administering to the mammal one or more sedatives.

65 (new). The method of Claim 64, wherein the one or more sedatives comprise at least one of diphenhydramine, doxylamine succinate, nitrazepam, midazolam, lormetazepam, flunitrazepam, flurazepam, oxazepam, bromazepam, triazolam, brotizolam, temazepam, chloral hydrate, zopiclone, zolpidem, tryptophan and/or zaleplon.

66 (new). The method of Claim 10, further comprising administering to the mammal one or more anxiolytics.

67 (new). The method of Claim 66, wherein the one or more anxiolytics comprise at least one of fluspirilene, thioridazine, oxazepam, alprazolam, bromazepam, lorazepam, prazepam, diazepam, clobazam, medazepam, chlordiazepoxide, dipotassium chlorazepate, nordazepam, meprobamate, buspirone, kavain and/or hydroxyzine.

68 (new). The method of Claim 10, further comprising administering to the mammal one or more anti-migraine agents.

69 (new). The method of Claim 68, wherein the one or more anti-migraine agents comprise at least one of almotriptan, zolmitriptan, acetylsalicylic acid, ergotamine, dihydroergotamine, methysergide, iprazochrome, ibuprofen, sumatriptan, rizatriptan, naratriptan and/or paracetamol.

70 (new). The method of Claim 10, further comprising administering to the mammal at least one additional active ingredient comprising one or more antidepressants, antipsychotics, sedatives, anxiolytics and/or anti-migraine agents, wherein the rotigotine or metabolite, prodrug or salt thereof and the at least one additional active ingredient are provided in separate dosage forms for administration by the same or different routes at the same or different times.

71 (new). The method of Claim 10, further comprising administering to the mammal at least one additional active ingredient comprising one or more antidepressants, antipsychotics, sedatives, anxiolytics and/or anti-migraine agents, wherein the rotigotine or metabolite, prodrug or salt thereof and the at least one additional active ingredient are administered in a single dosage form.

72 (new). The combination of Claim 28, wherein the one ore more antidepressants comprise at least one of sertraline, citalopram, partoxetine, fluoxetine, venlafaxine, milnacipram, mirtazapine, amitryptyline, imipramine, reboxetine, tranylcypromine, clorgyline, and/or nefazodone.

73 (new). The combination of Claim 9, wherein the one or more additional active ingredients comprise one or more antipsychotics.

74 (new). The combination of Claim 73, wherein the one or more antipsychotics comprise at least one of promethazine, fluphenazine, perphenazine, levomepromazine, thioridazine, perazine, promazine, chlorprothixene, zuclopentixol, prothipendyl, flupentixol, zotepine, benperidol, pipamperon, melperon, haloperidol, bromperidol, sulpiride, clozapine, pimozide, risperidone, quetiapine, amisulpride and/or olanzapine.

75 (new). The combination of Claim 9, wherein the at least one or more additional active ingredients comprise one or more sedatives.

76 (new). The combination of Claim 75, wherein the one or more sedatives comprise at least one of diphenhydramine, doxylamine succinate, nitrazepam, midazolam, lormetazepam, flunitrazepam, flurazepam, oxazepam, bromazepam, triazolam, brotizolam, temazepam, chloral hydrate, zopiclone, zolpidem, tryptophan and/or zaleplon.

77 (new). The combination of Claim 9, wherein the one or more additional active ingredients comprise one or more anxiolytics.

78 (new). The combination of Claim 77, wherein the one or more anxiolytics comprise at least one of fluspirilene, thioridazine, oxazepam, alprazolam, bromazepam, lorazepam, prazepam, diazepam, clobazam, medazepam, chlordiazepoxide, dipotassium chlorazeptate, nordazepam, meprobamate, buspirone, kavain and/or hydroxyzine.

79 (new). The combination of Claim 9, wherein the one or more additional active ingredients comprise one or more anti-migraine agents.

80 (new). The combination of Claim 79, wherein the one or more anti-migraine agents comprise at least one of almotriptan, zolmitriptan, acetylsalicylic acid, ergotamine, dihydroergotamine, methysergide, ipravochrome, ibuprofen, sumatriptan, rizatriptan, naratriptan and/or paracetamol.

81 (new). The combination of Claim 9, wherein the rotigotine or metabolite, prodrug or salt thereof and the one or more additional active ingredients are present in separate dosage forms adapted for administration by the same or different routes at the same or different times.

Serial No. 10/565,699
6102-000009/US/NP
Preliminary Amendment (Amendment B)
March 15, 2007

82 (new). The combination of Claim 9, wherein the rotigotine or metabolite, prodrug or salt thereof and the one or more additional active ingredients are present in a single dosage form.